MAR 1 8 2003

Wiener lab.
Especialidades para Laboratorios Clínicos

WIENER LABORATORIOS S.A.I.C. - Riobamba 2944 - 2000 Rosario - Argentina
Phone +54 (341) 432-9191/6 - Fax +54 (341) 432-5454/5555
Internet: http://www.wiener-lab.com.ar

Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K024305 **"**

Introduction

According to the requirements of 21 CFR 862.1150, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario – Argentina
Tel: 54 341 4329191
Fax: 54 341 4851986
Contact person: Viviana Cétola
Date Prepared: September 15, 2002

6-2 Device Name

Proprietary name: Wiener lab. Calibrador A *Plus*.
Common name: Multianalyte Calibrator.
Classification name: Calibrator, Multi-Analyte Mixture.
Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed ROCHE Calibrator for Automated systems (C.f.a.s.) (Cat. Nº759350).

6-4 Device Description

Calibrador A *plus* consists of lyophilized human serum containing the compounds usually determined in clinical chemistry laboratories in the appropriate concentrations to ensure optimum calibration of clinical chemistry procedures. Such concentrations are lot-specific and are provided in product insert.

6-5 Intended Use

For the quantitative calibration of WIENER LAB´s clinical chemistry procedures. **Calibrador A plus** is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

6-6 Equivalencies and Differences

The WIENER LAB. Calibrador A *Plus* calibrator is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed ROCHE Calibrator for Automated systems (C.f.a.s.)

The following table illustrates the similarities and differences between the WIENER LAB. Calibrador A *Plus* calibrator and the currently marketed ROCHE Calibrator for Automated systems (C.f.a.s.)

	ROCHE C.f.a.s.	**WIENER LAB. Calibrador A *Plus***
Intended Use	For use in the calibration of Roche methods on clinical chemistry analyzers.	For the quantitative calibration of WIENER LAB´s clinical chemistry procedures.
Format	Lyophilized pooled human sera with constituents added as required to obtain desired components levels.	

Continued on next page

	ROCHE C.f.a.s.	**WIENER LAB. Calibrador A *Plus***
Stability	Provided Reagents: stable in refrigerator (2-10ºC) until expiration date printed on label. Reconstituted calibrator: stable for 8 hours at room temperature, 2 days refrigerated or 1 month frozen (-20ºC), with exceptions noted in label.	
Levels	Single Level.	
Constituent Analytes	Albumin	Albumin
	Direct bilirubin	Direct bilirubin
	Total bilirubin	Total bilirubin
	Calcium	Calcium
	Cholesterol	Cholesterol
	Creatinine	Creatinine
	HDL Cholesterol	HDL Cholesterol
	Glucose	Glucose
	Iron	Iron
	Magnesium	Magnesium
	Phosphorus	Phosphorus
	Total proteins	Total proteins
	Triglycerides	Triglycerides
	Uric acid	Uric acid
	Urea	Urea
	Enzymes	
	Electrolytes	

6-7 Conclusion

Above mentioned data show substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 8 2003

Dr. Viviana Cetola
QC/QA Manager
Weiner Laboratorios S.A. I. C.
Riobamba 2944
2000 Rosario, Santa Fe
Argentina

Re: k024305
Trade/Device Name: Weiner lab. Calibrador A plus
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: December 13, 2002
Received: December 24, 2002

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024305

Device Name: Wiener lab.
Calibrador A plus

Indications For Use:

For the quantitative calibration of Wiener lab's clinical chemistry procedures. The "Calibrador A plus" is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Joan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024305